E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0580; FRL-10018-53]

Orthosulfamuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of orthosulfamuron (1-(4,6-dimethoxypyrimidin-2-yl)-3-{[2-(dimethylcarbamoyl)phenyl]sulfamoyl}urea) in or on Almond, hulls; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; Nut, tree, group 14-12. Nichino America, Inc. requested tolerances for these commodities under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0580, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center

(EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your

objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0580 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0580, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of March 3, 2020 (85 FR 12454) (FRL-10005-58), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8776) by Nichino America, Inc., 4550 Linden Hill Road, Suite 501,

Wilmington, DE 19808. The petition requested that 40 CFR 180.625 be amended by establishing tolerances for residues of the herbicide orthosulfamuron in or on almond hulls at 0.03 parts per million (ppm), small fruit vine climbing subgroup, except fuzzy kiwifruit (crop subgroup 13-07F) at 0.01 ppm, and tree nuts (crop group 14-12) at 0.01 ppm. That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has corrected the commodity definitions to reflect current Agency terminology.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for orthosulfamuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with orthosulfamuron follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness,

and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Orthosulfamuron is included in a group of herbicides referred to as sulfonylureas that control weeds through inhibition of the enzyme acetolactate synthase (ALS). The toxicological database for orthosulfamuron is complete and no additional data are required. Orthosulfamuron showed low acute toxicity by all routes and no dermal irritation or sensitization (Category IV) and was a mild eye irritant (Category III). The major target organs of orthosulfamuron are the liver, kidneys and thyroid gland, with effects generally observed at high doses following chronic oral exposure. No evidence of pre- and/or post-natal quantitative or qualitative susceptibility was observed, and the database overall did not show evidence of neurotoxicity.

Thyroid follicular cell tumors were observed at high doses in only one sex and one species, and there was no evidence of genotoxicity. Therefore, in accordance with the EPA Final *Guidelines for Carcinogen Risk Assessment* (March 2005), orthosulfamuron is classified as "Suggestive Evidence of Carcinogenicity."

Specific information on the studies received and the nature of the adverse effects caused by orthosulfamuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "*Orthosulfamuron. Human Health Risk Assessment for Proposed New Uses on Small Fruit Vine Climbing Subgroup, Except Fuzzy Kiwifruit (13-07F), Tree Nuts (14-12), Non-Bearing Citrus Fruit (10-10), and Non-Bearing Stone Fruit (12-12)*" (hereinafter "Orthosulfamuron Human Health Risk Assessment") on page numbers 25-35 in docket ID number EPA-HQ-OPP-2019-0580.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure

to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for orthosulfamuron used for human risk assessment can be found on page 13 in the Orthosulfamuron Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to orthosulfamuron, EPA considered exposure under the petitioned-for tolerances as well as all existing orthosulfamuron tolerances in 40 CFR 180.625. EPA assessed dietary exposures from orthosulfamuron in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for orthosulfamuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used

2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, *What We Eat in America* (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. Based on the available data for orthosulfamuron, which is summarized in Unit III.A., EPA has concluded that a nonlinear approach is appropriate for assessing cancer risk to orthosulfamuron. The chronic dietary reference dose (cRfD) is significantly lower than the dose that caused thyroid tumors in male rats, and therefore is protective of potential carcinogenicity. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for orthosulfamuron. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for orthosulfamuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of orthosulfamuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Screening groundwater-sourced drinking water exposure estimates were generated with the Pesticide Root Zone Model for GroundWater (PRZM-GW, version 1.07) for use in sulfonylurea dietary risk assessments. Rather than using chemical-specific estimated drinking water concentrations (EDWCs) following the usual assessment procedures, these coarse-screen

estimates should exceed upper-bound, chemical-specific EDWCs for any sulfonylurea (SU). This was achieved by using model inputs that represent the use pattern of highest exposure from any SU, the highest soil mobility of any SU residue of concern, and the highest persistence to any route of degradation over time. The resulting coarse-screen EDWC from PRZM-GW was used as the conservative estimate of exposure. The chronic dietary assessment for orthosulfamuron used the coarse-screen maximum daily concentration of 0.751 ppm.

3. *Non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Orthosulfamuron is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

The Agency has assessed orthosulfamuron, and its chemical class, sulfonylureas, and determined that the SUs do not share a common mechanism of toxicity (EPA-HQ-OPP-2011-04538-0024). The SUs share a core chemical structure with varying degrees of structural similarity based on individual substituents on either side of the molecule. In addition, the SUs share a pesticidal mode of action (MOA) (inhibition of acetolactate synthase (ALS)), although the function of ALS in humans is unknown and the relevance of this MOA in humans in unclear. Based on toxicity studies, the SUs do not share a common toxicological profile; instead the target organs vary among the class and are often non-specific, such as changes in body weight or general effects on the liver. Further dividing the SUs into subclasses based on the urea substituent did not result in a clear association of a target organ with any particular substructure.

Based on the weight of the evidence, which includes the lack of a common toxicological

profile, the uncertainty in the human relevance of ALS inhibition, and the lack of mammalian MOA data, a testable hypothesis for a common mechanism of action cannot be identified. Therefore, the Agency concludes that no common mechanism of toxicity exists among these pesticides and a cumulative risk assessment approach is not appropriate for this class of pesticides.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of the FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. The rationale for that decision remains the same as in the February 28, 2007 final rule establishing tolerances for a use on rice. See 72 FR 8928 (FRL-8113-4) for the full rationale in Unit III.D.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from

a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, orthosulfamuron is not expected to pose an acute risk.

2. *Chronic risk*: Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to orthosulfamuron from food and water will utilize 81% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for orthosulfamuron.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term or intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short-term and intermediate-term adverse effects were identified in the toxicity database (*e.g.* kidney and liver effects); however, orthosulfamuron is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term or intermediate-term risk), no further assessment of short-term or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risk for orthosulfamuron.

4. *Aggregate cancer risk for U.S. population*. As stated in Unit III.C.1.iii, EPA has concluded that the chronic reference dose (RfD) will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, which could result from exposure to orthosulfamuron. As there is no chronic risk of concern, EPA concludes that exposure to orthosulfamuron will not pose an aggregate cancer risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and

children from aggregate exposure to orthosulfamuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology utilizing high-performance liquid chromatography with tandem mass spectrometric detection (LC/MS/MS) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. Although EPA may establish a tolerance that is different from a Codex MRL, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for orthosulfamuron in any commodity.

V. Conclusion

Therefore, tolerances are established for residues of orthosulfamuron in or on Almond, hulls at 0.03 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.01 ppm; and Nut, tree, group 14-12 at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under the FFDCA section 408(d) in response to a

petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of the FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with

Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 4, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180-- TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.625,

a. Revise paragraph (a) introductory text;

b. Designate the table in paragraph (a) and add alphabetically the commodities "Almond, hulls"; "Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F"; and "Nut, tree, group 14-12".

The revision and additions read as follows:

§ 180.625 Orthosulfamuron; tolerances for residues.

(a) *General*. Tolerances are established for residues of the herbicide orthosulfamuron, including its metabolites and degradates, in or on the commodities in the table, below. Compliance with the tolerance levels specified in the following table is to be determined by measuring only orthosulfamuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-{[2-(dimethylcarbamoyl)phenyl]sulfamoyl}urea, in or on the following commodities:

Table to Paragraph (a)

Commodity	Parts per million
Almond, hulls	0.03
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.01
Nut, tree, group 14-12	0.01
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